

REMARKS

In the Office Action mailed September 25, 2006, the Examiner has required an election between the following Groups:

- I. Claims 1-7, drawn to sustained-release preparation prepared from double granules;
- II. Claims 1 and 8-11, drawn to sustained-release preparations prepared from double granules and containing a coat layer; and
- III. Claims 12 and 13, drawn to a method of preparing a sustained-release preparation.

To fully respond to the Restriction Requirement, Applicants hereby elect Group 1, claims 1-7, drawn to sustained-release preparations prepared from double granules, with traverse.

The Office Action has stated that the invention listed as Group I-III do not relate to a single general inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features for the reason that the common technical feature in all groups is a sustained-release preparation prepared from double granules and Kristensen *et al.* (U.S. Patent No. 5,807,583) teach a sustained-release preparation prepared from multiple granules. Applicants respectfully disagree.

The Office Action has mentioned Kristensen *et al.* in connection with Applicants' invention, due to a mistaken reading of the disclosure in the patent. Kristensen *et al.* disclose preparing pellets using only a single granulation process. In particular, Kristensen *et al.* disclose that the pellets were manufactured using pelletizing equipment in a process that involves: transferring the powders to a preheated mixing bowl, mixing the powders until the temperature reached 90°C, allowing the pellets to form, then tray-cooling and fractionating the product –which is a single granulation process. *See* Kristensen *et al.*, e.g., col. 6, lines 1-21.

Kristensen *et al.* actually discloses multiple unit dose formulations containing the pellets. *See* Kristensen *et al.*, e.g., col. 2, lines 57-58. Furthermore, Kristensen *et al.* states that “multiple unit dose formulation” is contemplated to mean “an oral dose formulation that at the appropriate location in the gastrointestinal tract, usually the stomach or intestines makes available a high number of similar units (e.g. pellets or granules).” *See* Kristensen *et al.*, e.g., col. 1, lines 14-18. Furthermore, Kristensen *et al.* explain “[t]he benefits of multiple unit dose formulations are primarily that the transport and distribution of

the free units in the various segments of the gastrointestinal tract are more uniform and reproducible than single unit dosage forms." See Kristensen *et al.*, e.g., col. 1, lines 25-29.

By contrast, Applicants teach preparing a preparation using two granulation processes. As recited in claim 1, Applicants' double granules are prepared by a primary granulation of drug and excipients, and by a secondary granulation of the granules that were obtained from the primary granulation. As Applicants have explained in paragraph [0009] of the originally-filed specification, performing a primary granulation and a secondary granulation has the advantage of "eliminating adhesion phenomenon of granules occurring during the tablet preparation, thereby allowing the production of tablet to be easy." Therefore, Kristensen *et al.* do not disclose Applicants' sustained-release preparations prepared from double granules.

Group I-III of the instant application relate to a single general inventive concept under PCT Rule 13.1 and they have the same or corresponding special technical features under PCT Rule 13.2, for the reason that the common technical feature in all groups is a sustained-release preparation prepared from double granules.

CONCLUSION

Applicant respectfully requests that the foregoing remarks be made of record in the file of the above-identified application. Applicant believes that the application is now in condition of allowance. If any issues remain in connection herewith, the Examiner is respectfully invited to telephone the undersigned to discuss the same.

No fee is believed to be due for this submission. Should any fees be required, however, please charge such fees to Jones Day Deposit Account No. 50-3013.

Respectfully submitted,

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